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09/926,622	02/20/2002	Paul Paquin	216324US0PCT	1127

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EXAMINER

BECKER, DREW E

ART UNIT PAPER NUMBER

1761

DATE MAILED: 11/09/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/926,622

Applicant(s)

PAQUIN ET AL.

Examiner

Drew E. Becker

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 August 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 24-43 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 24-43 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|-----------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 24-43 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The application does not appear to disclose treatments of "not more than three to five times", "increased flow rate and pressure drop bringing about shear stresses, cavitation, turbulence, and/or impingement", a pressure of "about 100 MPa to 300 MPa", a temperature range of "25 to 60°C", "at least 2 to 8 logs fewer" microorganisms, a "diary product", and a process "consisting of passing the liquid food product through the dynamic high pressure homogenizer three or five times".

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 24-43 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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5. Claim 24 recites a "liquid dairy product". It is not clear what a "liquid dairy product" is.
6. Claim 24 recites "pressurizing a liquid food product". It is not clear if this is the same material as the previously mentioned "liquid dairy product". It is not clear whether the processed material must simply be a liquid food, or not.
7. Claim 36 recites "consisting of passing the liquid food product through the dynamic homogenizer three or five times". However, it is not clear whether previously cited method steps are meant to be excluded or not.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. Claims 24-43 are rejected under 35 U.S.C. 103(a) as being unpatentable over DE 3903648A1 in view of Emulsiflex [website and in view of page 7, line 4 of applicant's remarks dated 1/17/06] and Degen et al [Pat. No. 5,401,523].

DE 3903648A teaches a process for reducing bacteria by pressurizing a liquid food material (page 4, lines 4-10, Figure 1, #3), passing the liquid food through a homogenizing valve for 1 minute (page 6, claims 5 & 8: Figure 1, #6), collecting the liquid food (Figure 1, #1), the pressure being 50-150 MPa (page 6, claim 4), the microorganisms including viruses and bacteriophages (page 4, lines 4-8), the liquid

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being carbohydrate and protein containing materials such as water (page 4, lines 4-10), a lack of denaturation, and operation at ambient temperatures which was conventionally considered to be about 25°C. DE 3903648A1 does not recite 3-5 passes through the homogenizer, processing raw milk and other dairy foods, the homogenizer being an Emulsiflex C-160, and reduction of specific bacteria such as *Listeria monocytogenes*, *Salmonella enteritidis*, and *Escherichia coli*. The Emulsiflex website teaches that the Emulsiflex C160 provided an effective reduction of *E. coli* in liquid foods, as well as the improved processing effects provided by 3-5 passes. It would have been obvious to one of ordinary skill in the art to incorporate the Emulsiflex C160 into the invention of DE 3903648A since both are directed to methods of processing liquid foods, since DE 3903648A already included a homogenizer, and since the Emulsiflex C160 homogenizer was known to be effective for reducing microbial populations via 3-5 passes (website). Degen et al teach a method for sterilizing raw milk comprising passing it through a homogenizer (Figure 1, #20) and elimination of microorganisms such as *L. monocytogenes*, *E. coli*, and *Salmonella* which were commonly found in milk (column 6, lines 18-22). It would have been obvious to one of ordinary skill in the art to process the raw milk of Degen et al in the process of DE 3903648A1, in view of Emulsiflex, since all are directed to methods of treating liquid food material, since DE 3903648A1 already envisioned protein-containing solutions to be used in the milk and dairy industry (page 4, line 5), since dairy foods were commonly sent through homogenizers as shown by Degen et al, and since liquid dairy foods commonly

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contained bacteria such as *E. coli*, *Salmonella*, and *L. cytogeneses* which needed to be eliminated as shown by Degen et al.

10. Claims 24 and 31-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Clark et al [Pat. No. 5,232,726] in view of Emulsiflex [website and in view of page 7, line 4 of applicant's remarks dated 1/17/06].

Clark et al teach a process for reducing bacteria by pressurizing a liquid food (column 2, line 42), passing the liquid food through a homogenizing valve for a full minute (Figure 1; column 3, line 38), collecting the liquid food (column 3, line 41), the pressure being 15,000 psi or greater (column 2, line 55), the microorganisms including bacteria such as *Saccharomyces cerevisia* (column 6, line 15), the liquid including citrus juice (column 6, line 21), citrus juice inherently including oils and water, a lack of denaturation, and a temperature of 25.5°C (column 3, line 46). Clark et al do not specifically recite 3-5 circulations and using an Emulsiflex C-160. The Emulsiflex website teaches that the Emulsiflex C160 provided an effective reduction of *E. coli* in liquid foods, as well as the improved processing effects provided by 3-5 passes. It would have been obvious to one of ordinary skill in the art to incorporate the Emulsiflex C160 into the invention of Clark et al since both are directed to methods of processing liquid foods, since Clark et al taught the use of any conventional homogenizer (column 2, line 52), and since the Emulsiflex C160 homogenizer was known to be effective for reducing microbial populations via 3-5 passes (website).

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11. Claims 25-30 and 38-43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Clark et al, in view of Emulsiflex, as applied above, and further in view of Degen et al [Pat. No. 5,401,523].

Clark et al and Emulsiflex teach the above mentioned concepts. Clark et al and Emulsiflex do not recite processing raw milk and other dairy foods, and reduction of specific bacteria such as *Listeria monocytogenes*, *Salmonella enteritidis*, and *Escherichia coli*. Degen et al teach a method for sterilizing raw milk comprising passing it through a homogenizer (Figure 1, #20) and elimination of microorganisms such as *L. monocytogenes*, *E. coli*, and *Salmonella* which were commonly found in milk (column 6, lines 18-22). It would have been obvious to one of ordinary skill in the art to process the raw milk of Degen et al in the process of DE 3903648A1, in view of Emulsiflex, since all are directed to methods of treating liquid food material, since Clark et al did not exclude other types of liquid foods such as milk, since liquid dairy foods were commonly sent through homogenizers as shown by Degen et al, and since liquid dairy foods commonly contained bacteria such as *E. coli*, *Salmonella*, and *L. cytogeneses* which needed to be eliminated as shown by Degen et al.

Response to Arguments

12. Applicant's arguments filed 8/24/06 have been fully considered but they are not persuasive.

Applicant argues that DE 3903648A does not teach an Emulsiflex C5 or C160. However, only claim 33 requires this.

Applicant argues that “not more than three to five times” was supported by page 6, line 23. However, page 6 does not include this phrase, or meaning.

Applicant argues that page 8 provided support for “increased flow rate and pressure drop bringing about shear stresses, cavitation, turbulence, and/or impingement”. However, page 8 does not even mention turbulence, or increased flow rate and pressure drop bringing about shear stresses, cavitation ,or impingement.

Applicant argues that page 13 and Figure 4 provide support for “about 100 MPa to 300 MPa”. However, page 13 and Figure 4 only provide support for individual pressure levels of 100 MPa, 200 MPa, and 300 MPa. There is not support for a pressure range of 100-300 MPa.

Applicant argues that page 13 provided support for “25 to 60°C”. However, page 13 only mentions treatment at individual temperatures of “25, 45, 55, or 60°C” (line 11), rather than a broad range of 25-60°C.

Applicant argues that Figures 4-7 provide support for “at least 2 to 8 log fewer microorganisms”. However, not all of the treatments shown in Figures 4-7 provided this effect.

Applicant argues that stainless steel devices were incapable of operating at pressures above 15,000 psi. However, this logic runs counter to many pressure treating devices which exclusively use stainless steel as a material. It is requested that applicant provide evidence to support this view.

Conclusion

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13. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Drew E. Becker whose telephone number is 571-272-1396. The examiner can normally be reached on Mon.-Fri. 8am to 4:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Milton Cano can be reached on 571-272-1398. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


DREW BECKER
PRIMARY EXAMINER

11/7/06